

Declaration by D. Lubda
In re application of Lubda et al.
Serial No.: 09/446,298



RECEIVED
OCT 16 2003
TC 1700

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Lubda et al.

Serial No.: 09/446,298

Filed 06/12/2000

For: HOLDING DEVICE FOR MONOLITHIC SORBENTS

Group Art Unit: 1771
Examiner: Chang, V.S.

DECLARATION

Honorable Commissioner of
Patents and Trademarks
Washington, D.C., 20231

SIR:

The Declarant, Dieter LUBDA, being duly warned, declares and says:

THAT he is a German citizen, residing at Bensheim, Germany;

THAT he is a Diploma engineer having studied at the Technische Fachhochschule Berlin (West), Germany, from 1980 to 1984;

THAT he graduated from the Technische Fachhochschule Berlin (West), Germany, in 1984;

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Services as First Class Mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: October 8, 2003

Name: Sharon McDaniel

Signature: Sharon McDaniel

THAT in 1984, he joined the Research and Development Department, Section Chromatography, of MERCK, Darmstadt, Germany;

THAT since 1984, he has been working in the field of separation materials and chromatography;

THAT he is author or co-author of numerous articles in the field of separation materials and chromatography, especially monolithic sorbents made of silica gel;

THAT he is familiar with the subject matter of the invention disclosed and claimed in U.S. Patent Application Ser. No. 09/446,298, by Lubda et al., of which he is a co-inventor (hereinafter referred to as APPLICATION);

THAT he is familiar with the subject matter disclosed in the cited references;

THAT the wall thickness of the Teflon tubing for the monolithic sorbent used for the experiments described in his declaration dated February 13, 2003 was 0.15 mm;

THAT experiments using another fluorinated polymer (polyvinylidene fluoride; PVDF) as cladding material for columns consisting of a monolith (diameter 5 mm; length 100 mm) resulted in rupture of the tube (wall thickness 1.75 mm) at 170 bar, a pressure well below results obtained when using the cladding material according to the present invention (260 bar) (see Appendix A and his prior declaration);

THAT the french document FR 2654835 A, a translation of which (relevant parts; see Appendix B) is subject of a separate declaration by Hans-Dieter Harders, describes that a tube of PEEK is expanded by applying internal pressure to the filled tube and THAT this elastic deformation is used for compressing the particulate sorbent material;

THAT a person skilled in the art would abstain from using such a deformable material for cladding a rigid monolith to be used in high pressure liquid chromatography (HPLC), because such deformation would cause leaks for the eluant between the tube and the monolith.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the APPLICATION or any patent issuing thereon.

Done, this October 01, 2003 at Darmstadt, Germany



Dieter Lubda

Déclaration by D. Lubda
In re application of Lubda et al.
Serial No.: 09/446,298

OCT 07 2003

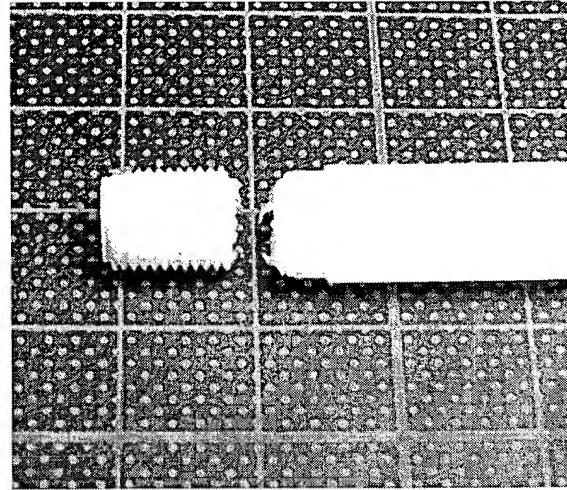
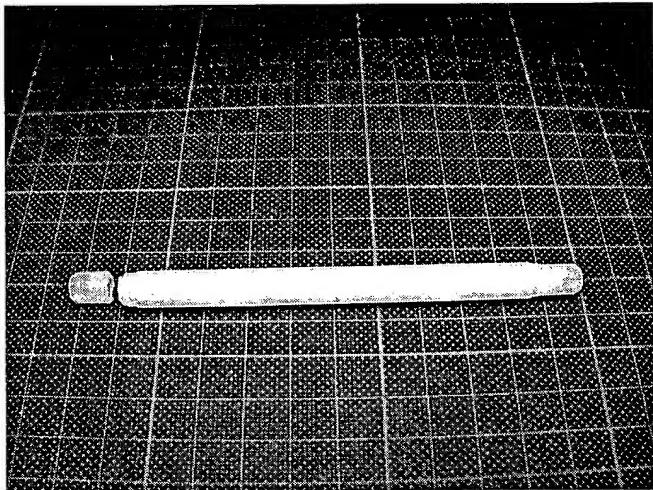
PATENT & TRADEMARK OFFICE

RECEIVED

OCT 16 2003

TC 1700

Enclosure A:



RECEIVED
OCT 16 2003
TC 1700

Enclosure B (Translation of FR 2654835 A):

page 1, lines 6 - 8

Par microcolonnes on désigne, au titre de la présente invention des colonnes de chromatographie dont le diamètre intérieur est inférieur ou égal à 0,5 mm. Les colonnes chromatographiques de ce type connaissent un intérêt croissant dans le domaine de l'analyse 10 chimique car elles permettent d'obtenir un pouvoir de résolution élevé sur de faibles quantités de matière. Elles se prêtent tout particulièrement bien à la chromatographie en phase liquide sous haute pression (HPLC). Les microcolonnes sont réalisées essentiellement en silice

The part starting with "Par microcolonnes on désigne" (line 6 above):

The micro columns of the present invention are designed as chromatographic columns having an internal diameter of less or equal 0.5 mm. ...

page 2, lines 1 - 4

Un second objectif de la présente invention réside dans la mise au point de colonnes dont les parois présentent un pouvoir de dilatation suffisant sous l'effet d'une surpression pour en faciliter le remplissage et en augmenter le compactage de la phase stationnaire. 05 Enfin un troisième objectif de la présente invention réside

The portion starting with "Un second objectif de la présente invention" (line 1 above):

A second objectiv of the present invention is to provide columns with walls sufficiently dilatable by elevated pressure and improving the compactness of the stationary phase.

page 2, lines 20 - 31

20 Les microcolonnes en PEEC sont exemptes des inconvénients
 signalés pour les colonnes en silice fondue. Plus particulièrement
 elles peuvent être manipulées aisément et coupées sans risquer de les
 briser. Cette possibilité permet d'éliminer l'extrémité de la colonne
 la moins compacte après son remplissage par une phase stationnaire. En
25 outre, par suite de l'élasticité des parois, il est possible de provo-
 quer lors du remplissage du tube en PEEC une dilatation de ses parois
 sous l'effet d'une surpression exercée dans la colonne par exemple
 jusqu'à 400 bar ; après remplissage, le retour à la pression normale
 permet la contraction des parois du tube ce qui a pour effet de contri-
30 buer au compactage du garnissage et par conséquent d'augmenter l'effica-
 cité des colonnes.

The part starting with "En outre" (line 24 above):

In addition, due to the elasticity of the wall (of the capillaries) it is possible to cause a dilatation (widening) of the wall during filling of the PEEK tube by the effect of excess pressure applied to the column up to e.g. 400 bar; after filling the pressure is returned to normal pressure and the walls of the tube contract thereby contributing to compacting the filling (garnissage) of the column thereby improving the efficiency of the column.

page 4, lines 1 - 5

 Pour l'obtention des microcolonnes selon l'invention on fait
 appel à des tubes en PEEC présentant un diamètre intérieur inférieur ou
 égal à 0,5 mm et compris de préférence entre 0,15 mm et 0,45 mm.
05 L'épaisseur de la paroi du tube n'est pas critique ; en général elle
 est comprise entre 0,65 mm et 0,80 mm.

The portion starting with "L'épaisseur de la paroi" (line 4 above):

The thickness of the wall of the tube is not critical; generally the thickness will be between 0.65 and 0.80 mm.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Lubda et al.

Serial No.: 09/446,298

Filed 06/12/2000

For: HOLDING DEVICE FOR MONOLITHIC SORBENTS

Group Art Unit: 1771
Examiner: Chang, V.S.

DECLARATION

Honorable Commissioner of
Patents and Trademarks
Washington, D.C., 20231

SIR:

The Declarant, Hans-Dieter HARDERS, being duly warned, declares and says:

THAT he is a German citizen, residing at Darmstadt, Germany;

THAT he is a biochemist having studied at the University of Tuebingen, Germany, from 1963 to 1970;

THAT he graduated from the University of Tuebingen, Germany, in 1970;

THAT he finished his PhD at the University of Tuebingen, Germany in 1973;

THAT he worked as assistant at the University of Stuttgart, Germany from 1973 to 1975;

CERTIFICATE OF MAILING

9726164_ha031001_usdecl_Ha.doc

I hereby certify that this correspondence is being deposited with the U.S. Postal Services as First Class Mail in an envelope addressed to: Commissioner of Patents, P O Box 1450, Alexandria, VA 22313-1450 on: October 7, 2003.

Name: Sharona McDaniel

Signature:

THAT from 1975 to 1989 he joined the Research and Development Department, Section Clinical Diagnostic, of MERCK, Darmstadt, Germany;

THAT from 1980 to 1984 he worked as transferee in different positions at EM Science, an affiliate of MERCK, Darmstadt, Germany, in the fields of clinical diagnostics and laboratory science;

THAT in 1990, he joined the Patent Department at MERCK, Darmstadt, Germany, since then he has been working in the field of laboratory science, especially in topics of chromatography and separation materials;

THAT in 1997 he passed the necessary exams and became enrolled in the list of European Patent Attorneys at the European Patent Office;

THAT he is familiar with the subject matter of the invention disclosed and claimed in U.S. Patent Application Ser. No. 09/446,298, by Lubda et al., of which he is a co-inventor (hereinafter referred to as APPLICATION);

THAT he is familiar with the subject matter disclosed in the cited references, including documents in French language, especially the document FR 2654835 A, cited by the present Examiner;

THAT the parts translated in the Appendix are representative for the disclosure and the teaching of FR 2654835 A;

THAT in the first part (page 1, lines 6 - 8) the field of the invention is characterized as related to capillary chromatography (internal diameter 0.5 mm or smaller);

THAT the second part (page 2, lines 1 - 4) relates to one object of the invention, which is to cause the tube to widen by applying an elevated pressure and use the elasticity of the tube material (PEEK) to exert a compacting pressure to the particulate sorbent;

THAT the third part (page 2, lines 20 - 31) relates to details concerning the object of the invention mentioned above;

THAT the fourth part (page 4, lines 1 - 5) is concerned with the thickness of the wall of the tube used in the invention of FR 2654835 A;

THAT these four parts of the french document FR 2654835 A, which have been translated (see Appendix) can be summarized as follows:

- a tube of PEEK is expanded by applying internal pressure to the filled tube;
- this elastic deformation of the tube is used for compressing the particulate sorbent material and thus used to increase the efficiency of the column;

THAT a person skilled in the art would abstain from using such a deformable material for cladding a rigid monolith to be used in high pressure liquid chromatography (HPLC), because such deformation would cause leaks for the eluant between the tube and the monolith.

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the APPLICATION or any patent issuing thereon.

Done, this October 01, 2003 at Darmstadt, Germany



Hans-Dieter Harders

Enclosure:

page 1, lines 6 - 8

Par microcolonnes on désigne, au titre de la présente invention des colonnes de chromatographie dont le diamètre intérieur est inférieur ou égal à 0,5 mm. Les colonnes chromatographiques de ce type connaissent un intérêt croissant dans le domaine de l'analyse clinique car elles permettent d'obtenir un pouvoir de résolution élevé sur de faibles quantités de matière. Elles se prêtent tout particulièrement bien à la chromatographie en phase liquide sous haute pression (HPLC). Les microcolonnes sont réalisées essentiellement en silice

The part starting with "Par microcolonnes on désigne" (line 6 above):

The micro columns of the present invention are designed as chromatographic columns having an internal diameter of less or equal 0.5 mm. ...

page 2, lines 1 - 4

Un second objectif de la présente invention réside dans la mise au point de colonnes dont les parois présentent un pouvoir de dilatation suffisant sous l'effet d'une surpression pour en faciliter le remplissage et en augmenter le compactage de la phase stationnaire.

05 Un troisième objectif de la présente invention réside

The portion starting with "Un second objectif de la présente invention" (line 1 above):

A second objectiv of the present invention is to provide columns with walls sufficiently dilatable by elevated pressure and improving the compactness of the stationary phase.

page 2, lines 20 - 31

20 Les microcolonnes en PEEK sont exemptes des inconvénients
signalés pour les colonnes en silice fondue. Plus particulièrement
elles peuvent être manipulées aisément et coupées sans risquer de les
briser. Cette possibilité permet d'éliminer l'extrémité de la colonne
la moins compacte après son remplissage par une phase stationnaire. En
25 outre, par suite de l'élasticité des parois, il est possible de provo-
quer lors du remplissage du tube en PEEK une dilatation de ses parois
sous l'effet d'une surpression exercée dans la colonne par exemple
jusqu'à 400 bar ; après remplissage, le retour à la pression normale
30 permet la contraction des parois du tube ce qui a pour effet de contri-
buer au compactage du garnissage et par conséquent d'augmenter l'effi-
cieté des colonnes.

The part starting with "En outre" (line 24 above):

In addition, due to the elasticity of the wall (of the capillaries) it is possible to cause a dilatation (widening) of the wall during filling of the PEEK tube by the effect of excess pressure applied to the column up to e.g. 400 bar; after filling the pressure is returned to normal pressure and the walls of the tube contract thereby contributing to compacting the filling (garnissage) of the column thereby improving the efficiency of the column.

page 4, lines 1 - 5

05 Pour l'abréviation des microcolonnes selon l'invention on fait
appel à des tubes en PEEK présentant un diamètre intérieur inférieur ou
égal à 0,5 mm et compris de préférence entre 0,15 mm et 0,45 mm.
L'épaisseur de la paroi du tube n'est pas critique ; en général elle
est comprise entre 0,65 mm et 0,80 mm.

The portion starting with "L'épaisseur de la paroi" (line 4 above):

The thickness of the wall of the tube is not critical; generally the thickness will be between 0.65 and 0.80 mm.